CTMS/CDUS SIG Teleconference
Meeting Minutes

Meeting Date	Wednesday, August 25, 2004 12-1 PM EDT
Attendees:	**Working group coordinator**: Harshawardhan Bal (Booz Allen & Hamilton) **Participants:**

Name	Email	Center
Rhoda Arzoomanian (SIG lead)	rza@medicine.wisc.edu	Wisconsin
Bob Lanese	Robert.Lanese@uhhs.com	Case Western
Mike Montello	montellom@ctep.nci.nih.gov	CTEP
Connie Kiefer	ckiefer@ctisinc.com	CTIS
William Price	wprice@theradex.com	CTMS
Lori Wangsness	wangsness.lori@mayo.edu	Mayo
Sharon Elcombe	elcombe@mayo.edu	Mayo
Christo Andonyadis	andonyac@mail.nih.gov	NCI
John Speakman	speakman@biost.mskcc.org	Sloan-Kettering
Brenda Crocker	crockerbl@msx.upmc.edu	UPMC
Sorena Nadaf	s.nadaf@vanderbilt.edu	Vanderbilt
Rick Magnan	magnan@jimmy.harvard.edu	Harvard university
Warren Kibbe	wakibbe@northwestern.edu	Northwestern University

Agenda

1. Review Face to Face Meeting
2. Update on Feedback since Face to Face Meeting
3. Discussion of Data Transmission Standards
4. Future Plans
5. Plans for next Face to Face Meeting, November 16-17, 2004
6. Next Teleconference: September 15th, 12-1pm EST

General discussion points raised by participants:	Data transmission standards: when clinical data was transmitted to CTMS/CDUS, it was not done securely and there was no consistent way of determining in a real time fashion what was sent, what was received, and whether there were errors in transmission. Traditional ftp based methods have the disadvantage that no response of receipt or error are obtained. Connie Kiefer mentioned that starting October 1, data submission to CDUS will be done via a secure ftp site and that instructions and guidelines manual will be made available shortly. William Price added that for CTMS data is sent via an encrypted email, which he felt meets the security requirements. Warren Kibbe described transmission standards for exchanging data between various federal agencies in a secure manner based on a web services model. The receiving system will then acknowledge the receipt of the data ("handshake") and respond by saying that the data was received, or if only parts of the data was received, or if all the packets in the data (for example, if it was adverse events data) passed all the requirements and was correctly parsed or not etc. A validation parser could be made available to all cancer centers to pre-screen data and to ensure that it will pass the requirements before sending it. A response that the data did pass the validation should still be sent by the receiving system. The group felt that validation at both levels would be very useful. Warren Kibbe asked the group if the validation parser could be built by the SIG and turned over to the NCI for implementation. Although CTEP and other groups were willing to participate in the testing for the parser, the group felt that the decision on building and implementing a parser should be left to the NCI. The functional differences between CDUS and CTMS were discussed. CDUS collects a summarized and highly structured and simplified data set and therefore has strict rules on content that is applied to generate a reject report. CTMS is not primarily a database; it is a monitoring service to review clinical studies in real time. What CTMS examines in detail varies from time to time and institution to institution and is a random subset audit process and so there are no strict rules on what CTMS get and data is submitted continuously and therefore it is difficult to automate it. Acknowledgement of data is done through a polling process which polls the server periodically and sends an email receipt. The email now provides the full listing of the file by name, state and size so that confirmation of accurate receipt of data can be obtained. An automated parsing review is not done; instead it is done by monitors as in a CRA monitoring operation and issues are dealt with a clarification request as in a drug study. The question of whether a CDUS parser that would give a response in seconds was a priority requirement was raised. The need to develop an ACES variant for CDUS was not considered a priority because CTMS dataset is a superset of the CDUS data and for the CDUS, the required data could be extracted. For a CDUS provided local capture system analogous to the way CTMS provides ACES as a local capture system

	within a transfer link. For the C3D project the clinical centers have their own in house system, for CTMS monitored protocols and for CDUS monitored protocols for each of which there are the appropriate CTMS and CDUS rules built into the front ends along with a data extractor that pulls out the formatted data for CTMS and CDUS transfer respectively. The group also discussed what the data capture element in caBIG for CTMS/CDUS reporting was. In essence this was the data parser with a set of clear and uniform rules that the NCI could formulate and that the cancer centers could use to apply to their local systems. The complexities of implementing the rules and changes to the rules in the context of the data-sharing paradigm of caBIG were discussed. A suggestion to develop a set of uniform rules that each center could apply in a standardized manner was put forth. This would lead to a document that can map the different codes used by different centers, for example, codes that are used for ethnicities etc., so that a uniform set of definitions can be developed. The mapping may be complicated given the existence of legacy systems and differences in the fields and concepts used across different centers. This may be approached by understanding the CDEs across organizations and utilizing a global conversion table of nomenclature that does the appropriate translations for the different variables that are permissible for a certain field (for example, for gender, male or female, M or F, or 0 or 1 etc). This document could lead to a single universally acceptable code for all the fields for all institutions. This transition could be made easier if the monitors (CTMS/CDUS) could also synchronize their codes (for example, CTMS uses M while CDUS uses 1 for male).
Action items	• Plan a test for a data parser at Northwestern and Vanderbilt to understand the issued involved in the parsing procedure. • To distribute the AE CTMS/CDUS survey to the people who hadn't got it after discussing with Joyce Niland • Perform a survey of CTMS & CDUS submission process and identify common workflows to enable centers to work together to develop a common way of reporting data.